

REMARKS

This amendment is responsive to the Office Action mailed on September 29, 2006. Currently 36 claims are pending in the present application, including independent Claims 1, 20 and 32. All of the claims stand rejected as obvious under 35 USC § 103, in view of various combinations of U.S. Pat. 5,315,455 ("Johnson"), U.S. Pat. 5,080,089 ("Mason '089"), U.S. Pat. No. 5,718,669 ("Marble"), U.S. Pat. 4,149,529 ("Copeland"), U.S. Pat. 4,552,132 ("Ruscigno"), U.S. Pat. 5,047,421 ("Goldsmith"), and U.S. Pat. 5,507,792 ("Mason '792"). Applicant thanks the Examiner for her thorough review of the present application.

1. Objections to Specification

The Examiner has noted several typographical errors in the specification. Appropriate corrections are made to the identified paragraphs. The Examiner's assistance in this regard is greatly appreciated.

2. Overview of the Disclosure

It is believed that the specific discussion of the claims that follows will be better understood by noting several aspects of the device disclosed in the present application. In the present application, "distal" and "proximal" is specifically defined with respect to the user's anatomy. For example, at page 7, beginning at line 2 and the present application states:

Throughout this document, the terms "proximal" and "distal" refer in general to the portion of the referenced element that is directed toward the "proximal" or "distal" portion, respectively, of the user when the system is in use, and wherein the lymph is understood to generally flow from a relatively distal portion of the user's anatomy to a relatively proximal portion.

An important aspect of the present invention is that the bladder produces a pressure gradient that decreases in the distal-to-proximal direction. The present inventor has discovered that: "This pressure gradient encourages the desired proximal flow of lymph in the user." (page 4, line 12).

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS^{PLLC}
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206 682 8100

This aspect of the invention is discussed throughout the application. For example, at page 7, beginning at line 23:

It will be appreciated by a person of skill in the art that the hydraulic pressure will exhibit a pressure gradient across the bladder 74 from a relatively high pressure, P_H (*see* FIGURE 2), at the inlet port 76, to a relatively low pressure, P_L , at the outlet port 78. The pressure gradient results naturally from the fluid flow through the bladder 74, including the restricting structures interior to the bladder 74 described below.

In fact, in the currently preferred embodiment of the invention, the bladder includes seal lines that are oriented to approximately direct the flow along a user's natural lymphatic pathways. This aspect of the preferred embodiment is noted, for example, at page 14, beginning at line 26:

The seal lines 312 are shown to be generally parallel to each other in FIGURE 6. In the preferred embodiment, the seal lines 312 are oriented to approximately follow the direction of physiologic lymph flow when the pad 300 is in use.

Another aspect of the present invention is the therapeutic pad system includes three different components that are applied to the user, the therapeutic pad or bladder, a liner with a plurality of compressible channels that is adapted to wrap about the bladder, and a binder that is adapted to wrap about the liner. This system is believed to be unique (independent of the uniqueness of the bladder), and as a combination provides many practical advantages over the prior art. For example, as noted on page 23, beginning at line 3:

Another benefit of the present invention is the flexibility provided by this system 200. It should be readily apparent that the system may be alternatively applied to the user in a number of different modalities to accommodate the particular needs and preferences of the user.

The disclosed system provides great flexibility in use modalities, wherein one or two of the three components can be used without the third component. For example, a user may desire to use only the liner and binder between thermal treatments, in order to retain mobility, or the liner may be omitted to provide more direct pressure on the user's limb. Therefore, the

combination of these three separable components in a single system is believed to be new, useful and nonobvious.

3. Relatively High Distal Pressure to a Relatively Low Proximal Pressure

As noted above, an important aspect of the present invention is that the bladder produces a distal-to-proximal pressure gradient that encourages the desired lymphatic flow. All three of the pending dependent claims are amended to emphasize this novel aspect of the invention.

In particular, Claims 1, 20 and 34 are amended to recite, in relevant part, a bladder having a distal portion with an inlet port into the flow space, and a proximal portion with an outlet port from the flow space, "such that during use a pressure gradient is produced across the bladder from a relatively high distal pressure to a relatively low proximal pressure."

The primary reference cited by the Examiner (Johnson) teaches directly away from the present claims, as amended herein. At column 2, beginning at line 59, Johnson states:

As an important element of the invention, the expansion of the cuff from inflation becomes greater in the area above the patella (where swelling is greatest) and the expansion is restricted in the area below the patella (where swelling is less). This causes the distal strap to be tensioned to a lesser degree than the proximal strap. It is well known medically and tests demonstrate that venous flow is far more sensitive to constriction in the region of the distal strap and less sensitive in the thigh under the proximal strap. Thus, by limiting tightening of the distal strap, little or no pressure is applied below the knee or in back of the knee and constriction of venous flow is further minimized.
(emphasis added)

Therefore, Johnson expressly teaches a lower pressure at the distal end, and a higher pressure at the proximal end as being an important element of the invention. Johnson, therefore, teaches directly away from the invention claimed in the present invention. As noted in the M.P.E.P. at § 2141.03 I. "In determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been

obvious, but whether the claimed invention as a whole would have been obvious." (emphasis in original). In the same section, part VI, the M.P.E.P. further notes, "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention."

In the present matter, Johnson teaches directly away from the presently claimed invention, and is therefore believed to be not a suitable reference for finding the present claims to be obvious.

Reconsideration of the rejection of the claims, in view of the present amendments, is respectfully requested.

4. Separable Bladder, Liner and Binder

As noted above, the present application discloses a system comprising a bladder, a separable liner and a separable binder. Even independent of the novelty of the bladder component, the system is believed to be novel and nonobvious over the prior art.

As noted above and in the application, the system comprising these three components enable the user to use the apparatus in a number of different modalities, to achieve different results. For example, without the bladder (for portable support), without the liner (for more direct pressure to the user, and/or with the liner and bladder reversed (for a more diffuse thermal treatment)).

This aspect of the invention is not believed to be disclosed, and the functionality is not believed to be present, in any of the cited prior art.

All of the independent claims are herein amended to clarify that the liner and binder are separable components, to clarify this aspect of the invention. Claims 1 and 20 are further amended to recite, in relevant part, "wherein the bladder, separable liner, and separable binder may be used in different combination to provide different treatment modalities."

5. Seal Lines Oriented to Direct Flow to Generally Align with the Direction of the User's Lymph Flow

Dependent claims 6, 18, 25 and 35 further recite seal lines in the bladder that direct the fluid flow through the bladder in a direction generally aligned with the user's lymph flow. The Examiner indicates on page 3 of the Office Action that Johnson discloses seal lines and spot welds oriented in the longitudinal direction of the leg. It is respectfully believed that Johnson does not disclose any seal lines, but rather discloses only spot welds (57) or a "tethering strap" (57'), neither of which is indicated to have any longitudinal extent.

In the Figures in Johnson (Fig. 1, 3, 4) the spot welds are indicated as circular elements (without orientation), and are not able to direct the flow to align with the user's lymph flow. Moreover, Johnson has a single "closable opening 26", and therefore does not contemplate having a fluid flow during use, except for filling and emptying the bladder (a Y-shaped siphon system (27, 29) is used to fill and empty the bladder). As we understand Johnson, the fluid reservoir for the bladder is elevated to provide a hydrostatic pressure in the bladder.

Page 6 of the Office Action also indicates that Mason et al. ('792) discloses flow deflecting seal lines. However, the seal lines are not indicated to be oriented to direct the fluid flow generally to align with the direction of the user's lymph flow.

For this additional reason, Claims 6, 18, 19, 25 and 35 are believed to contain allowable subject matter.

CONCLUSION

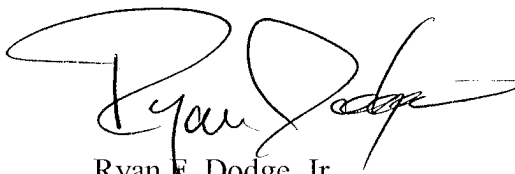
Claims 1-36 are pending in the present application. The independent claims are herein amended to include aspects of the present invention that are not found in the prior art. In particular, the amended claims clarify that a pressure gradient is produced across the bladder from a relatively high distal pressure to a relatively low proximal pressure. Also, the amended

claims recite that the liner and binder are separable components, which provided very useful flexibility to the system as discussed in the application, and is not found in the prior art.

In addition, Claims 6, 18, 19, 25 and 35 recite that the seal lines are oriented to direct the fluid flow to generally align with the direction of the user's lymph flow. This novel aspect is also not believed to be found in the prior art. Entry of the amendments, and a favorable disposition of the claims is respectfully requested.

Respectfully submitted,

CHRISTENSEN O'CONNOR
JOHNSON KINDNESS^{PLLC}

A handwritten signature in black ink, appearing to read "Ryan Dodge", with a large, stylized loop at the end.

Ryan E. Dodge, Jr.
Registration No. 42,492
Direct Dial No. 206.695.1724

RED:lpz

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS^{PLLC}
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100